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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,987	05/25/2006	Tatsuhiko Kodama	14875-152US1 C1-A0306P-US	1443

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
03/31/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/550,987	KODAMA ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER H. YAEN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-32,34-36 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *16-29,32,34-36,38,39 and 42-45* is/are rejected.

7)☒ Claim(s) *30,31,40 and 41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/19/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Re: Kodama *et al*

1. The amendment filed 2/19/2009 is acknowledged and entered into the record. Accordingly, claims 1-15,33, and 37 are canceled without prejudice or disclaimer, and claims 44-45 are newly added.

2. Claims 16-32,34-36 and 38-45 are pending.

3. Upon further review and reconsiderations, withdrawn claims 17,29, and 39 are rejoined with other examined claims in view of the persuasive arguments set forth by the applicant in the paper filed 2/19/2009.

4. Claims 16-32,34-36, and 38-45 are examined on the merits.

Claim Rejections Maintained - Provisional Double Patenting

5. The rejection of claims 16-18, and 20-22 under provisional obvious type double patenting over USSN 10/497,900 is maintained for the reasons of record. Applicant argues that the final scope of the claims of the co-pending application have not been determined because the application has not been allowed. Applicant further argues that the co-pending application also does not teach overlapping subject matter because the claims of the instant invention are limited to those antibodies that "inhibit peptide uptake". Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claims of the co-pending application are drawn to an antibody that binds to a PepT peptide. The claims are further limited to specifically recite PepT1. The claims of

the instant application are drawn to a genus antibodies that bind to peptide transporters, thereby making the claims of the instant invention a broader or genus type claim. Because a species always anticipates or renders obvious a genus, the claims of the co-pending application encompasses overlapping subject matter. Moreover, the functional language recited in the instant application is an intended use of the antibody and because the claims are drawn to the product per se, the claims of the co-peinding applicant are deemed to also have this property.

MPEP Ch. 804 teaches "[o]ccasionally, the examiner becomes aware of two copending applications that were filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. In re Mott, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); In re Wetterau, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one

application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Therefore, the rejection of claims under provisional obvious type double patenting is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

6. The rejection of claims 16,18-27, and now claim 17 under 35 USC § 103(a) as being obvious over Liang *et al* and Liu *et al* in view of Campbell, Winters *et al* and, Basu *et al* is maintained for the reasons of record. Applicant argues that the cited references do not establish a prima facie case of obviousness. In particular, applicant contends that the examiner has not supported the rejection of obviousness with "a reason one of ordinary skill would have combined the prior art teachings to generate a monoclonal antibody with the characteristics specified in the claims". Applicant further argues that routine work is not enough to render an invention obvious, and that the production of an antibody to the claimed peptide transporters has not be supported by any motivation in the prior art and that the generation of an antibody might not be producible. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The Board of Patent Appeals and Interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is prima facie obvious. See *Ex parte Ehrlich*, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int.

1987), *Ex parte Sugimoto*, 14 USPQ 2d 1312 (PTO Bd. Pat. App. & Int. 1990). The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). In the instant case, since the antigens of PepT1 and PepT2 were already fully characterized and made available to those of skill in the art, it would have been obvious to make antibodies, especially monoclonal antibodies to these antigens. In addition, those of skill in the art are well versed at the construction of man made antibodies such as chimeric and humanized antibodies (see Winter *et al*). Therefore, those of skill in the art would have been motivated to make any antibody (i.e. monoclonal, chimeric, humanized) to PepT1 and PepT2. Therefore, the rejection of claims is maintained for the reasons of record.

NEW REJECTIONS

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 16,17,20-29,32,34-36,38-39, and 42-45 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DESCRIPTION REJECTION.

The specification teaches that a "peptide transporter" encompasses a general class of proteins either import peptides or export peptides from a cell, in addition, they can also be classified by the means of energy that they use to accomplishes these transportation activities. Therefore, the recited phrase of "peptide transporter" encompasses more that the what is disclosed in the instant specification. The written description in this case has only set forth antibodies that bind to PepT1 and PepT2 and therefore the written description is not commensurate in scope to the claims that read on a large and general class of peptide transport proteins.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification has only set forth 2 species within the large and broad class of peptide transporters claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. v. Gen-Probe Inc.* are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *University Of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed.

Cir. 1997). The Court stated that" [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. at 1567, 43 USPQ2d at 1405. The court also stated that:

> *a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.*

Id. at 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See *Enzo Biochem, Inc. V. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The *Enzo* court adopted

the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics .... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* at 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in *Lilly* and *Enzo* were DNA constructs *per se*, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot also adequately describe a method of using that product.

Thus the instant specification may provide an adequate written description of peptide transporters, per *Lilly*, by structurally describing representative peptide transporters proteins or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per *Enzo*, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification has set forth 2 species of peptide transporters that fall within one of the 4 possible classifications of peptide transporters (i.e. those that are proton concentration dependent) and yet the claims are drawn to antibodies and

methods of using those antibodies that bind to a much broader class of peptide transporters, and thus the invention does not satisfies either the *Lilly* or *Enzo* standards.

Further, the specification also fails to describe a representative number of protein transporters by the test set out in *Lilly* because the specification describes only PepT1 and PepT2. Therefore it necessarily fails to describe a representative number of such species. Thus the specification does not provide an adequate written description of protein transporters that is required to practice the claimed invention. Since the specification fails to adequately describe the product to which the claimed method uses, it also fails to adequately describe the method.

Finally, the court held there to be a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514. Further, a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. *Id.* at 1350. In the instant case, applicant has only defined two species of a large and potentially uncharacterized genus of antigens. Thus in the absence of antigen identity and antigen structure, those of skill in the art would not be able to readily determine that the applicant was in possession of the broad class of antibodies claimed. Moreover, in the absence of the antibody, the claimed method of using the antibody would also lack adequate written description.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER H. YAEN whose telephone number is (571)272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher H Yaen/
Primary Examiner, Art Unit 1643